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December 5, 2022

Via E-Mail and ECF Filing

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Hon. Kenneth M. Karas
The Hon. Charles L. Brieant Jr.
Federal Building and United States Courthouse
Courtroom 521
300 Quarropas St.
White Plains, NY 10601

**Re: *ProImmune, et al. v. Three Aminos, et al., Case No. 22-cv-08227-KMK –
Pre-motion Letter***

Counsel:

Pursuant to Section II.A of the Individual Rules of Practice of the Honorable Kenneth M. Karas, we write on behalf of Plaintiff The ProImmune Company, LLC and Third-Party Defendant Albert Crum, M.D. (collectively, “ProImmune”) to respectfully inform Defendants and Counterclaimants Laura Lile, M.D. and Three Aminos, LLC (collectively, “Three Aminos”) that the Counterclaims they filed on November 17, 2022 should be dismissed, as they suffer from incurable defects. First, all of Three Aminos’ claims are duplicative of the claims it filed in both Case No. 22-cv-07242 and Case No. 22-cv-08229. This is improper, and all of Three Aminos’ claims are thus subject to dismissal. Separately, Three Aminos’ first cause of action for false patent marking fails for lack of standing, and its second cause of action for declaratory judgment fails to state a claim for relief. We therefore request that Three Aminos voluntarily dismiss its Counterclaims in this action.

I. Summary of Relevant Allegations in Counterclaims¹

In 2020, ProImmune and Three Aminos entered into a series of agreements related to Immune Formulation 200®, a dietary supplement developed, manufactured, and sold by

¹ ProImmune accepts the facts of Three Aminos’ allegations only for purposes of this pre-motion letter.

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ProImmune. Dr. Lile recognized the potential of Immune Formulation 200®, not just as a supplement, but also as a possible treatment for, among other things, COVID-19.

Given this potential, ProImmune and Three Aminos entered into a series of agreements related to Immune Formulation 200®. First, Three Aminos agreed to be a non-exclusive distributor of Immune Formulation 200®.

In addition, ProImmune and Three Aminos executed a Pharmaceutical Commercialization Agreement (“PCA”). The PCA created a joint venture whereupon both ProImmune and Three Aminos would equally co-own and co-manage a new company: Innate FFAAP Medicines, LLC (“Innate”). Innate was intended to be a holding company for two subsidiary operating companies: Prothione, LLC and Lipinol LLC.

Each of Prothione LLC and Lipinol LLC are wholly owned by Innate and are intended to develop and commercialize, through FDA marketing approval, two different formulations incorporating Immune Formulation 200®. First, Prothione LLC was created to commercialize a formulation of Immune Formulation 200® called “Prothione” for purposes of treating COVID-19. Second, Lipinol LLC was intended to commercialize a different formulation incorporating Immune Formulation 200® which is intended to treat high cholesterol (dyslipidemia) and is called “Lipinol.”

At the time ProImmune and Three Aminos executed the PCA, they also agreed to license agreements for Prothione and Lipinol (“License Agreements”). Pursuant to these License Agreements, ProImmune licensed patents to the new entities, including RE42,645 (the ‘645 Patent) and RE39,734 (the ‘734 Patent), which both relate to Immune Formulation 200®. Three Aminos also appears to be claiming, although both the claim itself and the way it is written is confusing to ProImmune, that it was additionally required to take a license to patent 9.229,014 (the ‘014 Patent) for the same purposes. The ‘645, ‘734 and ‘014 Patents are collectively referred to herein as the “Challenged Patents.”

Separately, ProImmune and Three Aminos entered into the Oxidative Stress Kit Commercialization Agreement (“Kit Agreement”) for the purpose of developing, digitizing, and commercializing ProImmune’s analog kit for measuring oxidative stress (“Oxidative Stress Kit”). The Kit Agreement also created a new entity, Stress Watchers Oxidative Stress Test Methods, LLC (“Stress Watchers”). One reason why ProImmune is confused regarding the apparent claim that the ‘014 Patent covers Immune Formulation 200® is that Defendants also note that the ‘014 Patent claims a method to measure oxidative stress rather than a compound such as Immune Formulation 200®.

Three Aminos alleges that throughout the negotiation of these agreements, ProImmune represented that Immune Formulation 200® was covered by the ‘645 and ‘734 Patents.

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Three Aminos now alleges that these representations were fraudulent, and that the Challenged Patents do not cover Immune Formulation 200. Three Aminos also alleges that ProImmune is in breach of the various agreements due to the purported invalidity of the Challenged Patents. Three Aminos further alleges that ProImmune engaged in false patent marking under 35 U.S.C. § 292.

II. Procedural History

ProImmune initiated this action by filing a Verified Complaint in the Supreme Court of New York alleging that Three Aminos has breached the various agreements by, among other things, failing to fund the operations of the joint entities, failing to take steps to commercialize Prothione and Lipinol, and failing to develop and commercialize the Oxidative Stress Kit. ProImmune also filed an action in the Supreme Court of New York asserting derivative claims on behalf of Innate, Prothione, Lipinol, and Stress Watchers (“Derivative Suit”).

Separately, ProImmune also filed an action in the Southern District of New York on August 24, 2022, alleging that Three Aminos breached the parties’ distribution agreement and that Three Aminos violated federal trademark laws. (Case No. No. 22-cv-07242-KMK) (“Trademark Suit”).

Three Aminos subsequently removed both of the state court actions to this Court and filed Counterclaims in each of the three suits. On November 17, 2022, Three Aminos filed Amended Counterclaims in each of the three actions. The Counterclaims in all three cases are virtually identical.

III. The Counterclaims Should Be Dismissed²

A. The Counterclaims Here are Duplicative of the Counterclaims in the Derivative and Trademark Suits

Three Aminos’ counterclaims are subject to dismissal on the grounds that they are entirely duplicative of the counterclaims Three Aminos asserted in both the Derivative and Trademark Suits. “[A] plaintiff has no right to maintain two actions on the same subject in the same court, against the same defendant at the same time.” *Sacerdote v. Cammack Larhette Advisors, LLC*, 939 F.3d 498, 504 (2d. Cir. 2019). Given this, “[a]s part of its general power to administer its docket, a district court may stay or dismiss a suit that is duplicative of another federal court suit.” *Curtis v. Citibank, N.A.*, 226 F.3d 133, 138 (2nd Cir. 2000).

² Given that Three Aminos’ Counterclaims in this action are identical, the arguments set forth herein mirror those that ProImmune previously set out in a pre-motion letter in the Trademark Suit.

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“[T]he general principle is to avoid duplicative litigation.” *Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976).

Here, a comparison of the three sets of Counterclaims filed by Three Aminos reveals that the allegations and claims therein are nearly identical. (Compare ECF No. 26 with Case No. 07242, ECF No. 23, and Case No. 22-cv-08229, ECF No. 15.) All three sets of Counterclaims are asserted by and against the same parties. In all three, Three Aminos alleges the same alleged false patent marking, the same breaches of contract, the same purported misrepresentations, the same claims for misappropriation of trade secrets, and seeks the same declaratory relief. Three Aminos is not permitted to waste the parties’ and the Court’s resources by pursuing wholly redundant claims in three separate proceedings. *Sacerdote*, 939 F.3d at 504 (rule against duplicative litigation bars a second suit involving “the same parties . . . the same rights asserted and the same relief prayed for;” where the requested relief is “founded upon the same facts,” and the “essential basis of the relief sought [is] the same.”); *Davis v. Norwalk Econ. Opportunity Now, Inc.*, 534 F. App’x 47, 48 (2d Cir. 2013) (affirming dismissal of duplicative suit: “[T]he facts alleged in the two complaints are not simply related in time, space and origin. They are nearly identical.”)

Thus, Three Aminos’ Counterclaims in this Action should not move forward. ProImmune respectfully requests that Three Aminos voluntarily dismiss these claims.

B. Three Aminos Lacks Standing to Bring a Claim for False Patent Marking under 35 U.S.C. § 292

Separately, Three Aminos’ claim for false patent marking must be dismissed, as Three Aminos lacks standing to assert such a claim here.

Section 292 provides that “[w]hoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word ‘patent’ or any word or number importing that the same is patented, for the purpose of deceiving the public,” violates federal law. Three Aminos alleges that ProImmune has falsely marked Immune Formulation 200® as patented, when it is purportedly not.

Critically, however, only a plaintiff that has “‘suffered a competitive injury as a result of a violation’ of the marking statute” can bring a claim under this Section. *Infinity Headwear & Apparel, LLC v. Jay Franco & Sons, Inc.*, No. 15-CV-1259 (JPO), 2017 WL 3309724, at *5 (S.D.N.Y. Aug. 2, 2017). A competitive injury is “[a] wrongful economic loss caused by a commercial rival, such as the loss of sales due to unfair competition; [or] a disadvantage in a plaintiff’s ability to compete with a defendant, caused by the defendant’s unfair competition.” *Sukumar v. Nautilus, Inc.*, 785 F.3d 1396, 1400 (Fed. Cir. 2015). “[A]n injury is only a ‘competitive injury’ if it results from competition, and a potential competitor is engaged in competition if it has attempted to enter the market, which includes intent to enter the market and action to enter the market.” *Id.* at 1402.

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Here, Three Aminos does not and cannot allege any such injury. Three Aminos is a *distributor* of ProImmune's Immune Formulation 200® product. It does not allege that it has been thwarted from entering the market with its own product as a result of the patent marks on Immune Formulation 200®, or that it has taken any actual steps toward such market entry. To the contrary, Three Aminos simply sells Immune Formulation 200® (albeit with an improperly altered label and trademark).

Three Aminos alleges, in cursory fashion, that it has suffered injury because the distribution agreement between it and ProImmune contains “non-competition and non-circumvention provisions” which “purport to prevent Three Aminos from developing or marketing directly or indirectly products which are substantially similar with Immune Formulation 200.” (Amended Counterclaim ¶ 124.) But by Three Aminos' own admission, these restrictions are *contractual*—they were not caused by any alleged false patent marking, but rather they are the result of an arms' length negotiation between sophisticated parties. Because this purported injury was not “a result of a violation” of the marking statute (35 U.S.C. § 292), it does not confer standing on Three Aminos to bring this claim. And in any event, as noted, Three Aminos has not alleged that, absent these provisions, it even would enter the market with its own product to try to compete with ProImmune, or that it has taken any steps to do so. *See Sukumar*, 785 F.3d at 1402 (“Dreaming of an idea but never attempting to put it into practice is insufficient. Otherwise, market entry is too speculative and, thus, competition cannot be harmed by the false marking.”)

In sum, Three Aminos lacks standing to bring a claim under 35 U.S.C. § 292.

C. Three Aminos' Counterclaim for Declaratory Relief is Defective

Three Aminos' second cause of action for declaratory relief seeks a declaratory judgment that no patent covers Immune Formulation 200®. Three Aminos, however, has failed to allege facts demonstrating that there is a justiciable case or controversy regarding the scope of ProImmune's patents.

It is firmly established that a “party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy.” *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95 (1993); *see also Diamonds.net LLC v. Idex Online, Ltd.*, 590 F. Supp. 2d 593, 601 (S.D.N.Y. 2008) (“a party challenging the validity of a patent always bears the ultimate burden of showing that an actual controversy supports the action, regardless of whether the challenge is brought via a freestanding action or a counterclaim”). A justiciable controversy requires some affirmative act by the patentee that suggests a controversy of sufficient immediacy and reality, such as threatening an “infringement suit,” “demanding the right to royalty payments,” “or creating a barrier to the regulatory approval of a product that is necessary for marketing.” *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (citation omitted).

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Put differently, a claim for a declaration of patent invalidity presents a case or controversy only when the party seeking declaratory relief intends shortly to take some action inconsistent with the rights of the patent holder. “If a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither ‘immediate’ nor ‘real’ and the requirements for justiciability have not been met. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008).

Here, ProImmune has not alleged the existence of an actual case or controversy regarding the scope of ProImmune’s patents. Specifically, Three Aminos does not allege that it has taken *any* steps toward conducting infringing activity, as required under the law. *Cat Tech.*, 528 F.3d at 880. In fact, **Three Aminos cannot allege this with respect to the ‘645 and ‘734 Patents because they have expired.**³ By definition, therefore, there can be no threat of future enforcement of the patents, and no controversy of “sufficient immediacy and reality” to warrant declaratory relief. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007); *see Sony Elecs., Inc. v. Soundview Techs., Inc.*, 359 F. Supp. 2d 173, 176 (D. Conn.), *adhered to on reconsideration*, 375 F. Supp. 2d 99 (D. Conn. 2005) (“[B]ecause the patent has expired, there is no risk that future Sharp products will be accused of infringing Soundview’s patent. In these circumstances, to decide the declaratory judgment counterclaims would be to render an advisory opinion with no effect on the parties before the court.”). Any purported need for a declaratory judgment is moot. *U.S. Rubber Recycling, Inc. v. Encore Int’l, Inc.*, No. CV 09-09516 SJO OPX, 2011 WL 311014, at *9 (C.D. Cal. Jan. 7, 2011) (“[O]nce the patent had expired, the claim for a declaratory judgment of invalidity became moot[.]”)

There is also no case or controversy with respect to the ‘014 Patent. ***That patent is owned by Stress Watchers, not ProImmune.*** As required by Section 3.1 of the Kit Agreement, ProImmune long ago sold and duly assigned the ‘014 Patent to Stress Watchers.

Aside from which, it is difficult to understand the basis for a request for a declaratory judgment that the ‘014 Patent does not cover Immune Formulation 200®, when that patent claims a method for measuring oxidative stress rather a compound intended for consumption. The ‘014 Patent is not part of the PCA or the License Agreements.

In any event, even putting aside the expiration of the ‘645 and ‘734 patents and the assignment of the ‘014 patent, there is still no case or controversy. When determining whether a justiciable controversy exists regarding the status of a patent, courts must look to the claims asserted (or threatened to be asserted) **by the patent-holder**—not by the counterclaimant. *See Speedco, Inc. v. Estes*, 853 F.2d 909, 912 (Fed. Cir. 1988) (to determine the right to declaratory relief, courts look “not to the declaratory judgment complaint, but to

³ The Court may take judicial notice of the expiration of the patents, as this status can be “readily determined from sources whose accuracy cannot reasonably be questioned determined by reference to public documents.” Fed. R. Evid. 201; *see also MacSwan v. Merck & Co.*, No. 1:20-CV-1661, 2022 WL 1415031, at *3 (W.D.N.Y. May 4, 2022) (“The court takes judicial notice of patent expiration dates[.]”)

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the action that the declaratory defendant would have brought”); *Univ. of Kentucky Rsch. Found., Inc. v. Niadyne, Inc.*, No. CIV. 13-16-GFVT, 2013 WL 5943921, at *6 (E.D. Ky. Nov. 5, 2013) (“In evaluating Niadyne’s declaratory judgment counterclaim under this rule, the relevant focus is not on Niadyne’s claim for declaratory judgment, but on the hypothetical complaint expressing the threatened action that UKRF (the declaratory defendant) would have brought against Niadyne (the declaratory judgment plaintiff).”)

Here, this is not a hypothetical exercise, as ProImmune has already asserted claims against Three Aminos—none of which are dependent on the patents being valid or enforceable. (See, generally, Complaint.) ProImmune has not brought claims for infringement, or to collect patent royalties, or any other cause of action that requires the patents to be enforced or otherwise adjudicated. Thus, there is simply no basis for a declaration that the patents are limited in scope.

In short, Three Aminos will not be able to obtain a declaratory judgment regarding the Challenged Patents.

As always, we are available if you would like to discuss any of these issues further.

Sincerely,

A handwritten signature in black ink, appearing to read "Ryan Abbott", is centered below the word "Sincerely,".

Ryan Abbott
of BROWN, NERI, SMITH & KHAN LLP